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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,870	WINDLE ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-132* is/are pending in the application.

4a) Of the above claim(s) *66-77,79-88,90-110,112-121 and 123-132* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78,89,111 and 122* is/are rejected.

7)☐ Claim(s) *78,89,122* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/9/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 67-132 are pending.

Claims 78,89,111 and 122 are under consideration; all other claims stand withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I, species SEQ ID NO 4 in the reply filed on July 28, 2005 is acknowledged. The traversal is on the ground(s) that inventions of Groups I-IV are related one to the other and therefore examination of the entire application cannot constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term distinct≅ is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-IV are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Gene therapy has obtained a separate status in the art from active or passive immunization with protein antigens. In the instant case a burden has been established in showing that the inventions of Groups I-IV are classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the

burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example genes and nucleotide sequences would not necessarily provide disclosure on humeral immune responses and antibodies to protein antigens. Additionally, it is submitted that the inventions of Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP ∋ 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ∋ 103(b),≅ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ∋ 804.01.

Information Disclosure Statement

1. The information disclosure statement filed May 9, 2002 has been considered.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

3. Claims 78, 89 and 122 are objected to because of the following informalities:

4. Claims 78 and 89 depend from a withdrawn claim and therefore do not specifically set forth all of the claim limitations under consideration.

5. Claim 122 depends from claim 120, a withdrawn claim which recites non-elected invention therefore does not specifically set forth all of the claim limitations under consideration. Claim 122 also recites non-elected species of invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 111 is directed to a gene that is not isolated and purified and therefore is directed to a product of nature; the claimed invention is directed to non-statutory subject matter. This rejection could be obviated by amending the claim to recite the phrase -----isolated and purified--------.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 78, 89, 111 and 122 (method of making vaccine preparations that comprise SEQ Id No 4, derivative, mutant or variants thereof) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claimed invention is directed to genes that comprise SEQ ID NO 4, as well as genes that are derivative, mutant or variants thereof for induction of a protective immune response in a host. What the sequences that are 5' and 3' and contained within the many operons of the bacterial genes, as well as what all of the claimed alternations are that would meet the functionally defined recitation of being a vaccine without knowledge of the specific structure

can not be reasonably ascertained based upon the functional recitation of the term "vaccine".

The specification discloses SEQ ID NO 4 which is a surface layer protein known to be associated with virulence factors and resistance to host immune factors but the claimed genes that have been altered have not been described for all of the bacteria encompassed by the scope of the claims. The specification has not described what derivatives, fragments, mutants or variants would serve to induce a protective immune response when the coding nucleotide sequence is administered to a host. A description of a genus may be achieved by means of a recitation of a representative species, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398-1412, 1406 (Fed. Cir. 1997).

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of bacteria that have alterations in their gene loci (nucleic acid molecules that encode a plurality of proteins) that encode proteins that will induce a protective immune response and therefore function as a vaccine. There is no description of where or how the alterations must be made in the coding sequence SEQ ID NO 4, or in the derivative, mutant, fragment or variant genes of SEQ ID NO 4 to achieve the recited effect. The specification proposes to discover other members of the genus by using sequence homologies and introduction of alterations based upon what is already known. There is no description, however, of what changes can be introduced into the claimed genes in order to obtain or maintain the essential structural components so the nucleotide sequence will not only be immunogenic, but also induce a protective immune response. No repeatable method for

obtaining the desired effect has been disclosed. Altered genes (fragments, derivatives, variants, mutants of SEQ Id NO 4) that have structural features that could distinguish the claimed vaccines from others excluded are missing from the disclosure.

A representative number of species for the claimed genus of vaccine genes that are within the genus of hypervariable coding sequences of SEQ ID NO 4 (fragment, variant, derivative, mutant), have not been described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to

a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Genes that are allelic variants are intended to be encompassed by the scope of the claims. However, no genes with alterations in allelic variant gene loci that are variants, derivatives, mutants or fragments of SEQ ID NO 4 have been described. Sufficient support for the generic claims has not been provided. See the Interim Written Description Guild lines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

11. Claims 78, 89, 111 and 122 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

16. Claims 78, 89, 111 and 122 are directed to a vaccine which comprises SEQ ID NO 4, a derivative, fragment or mutant or variant of SEQ ID NO 4, wherein the derivative, fragment or mutant or variants would include nucleic acid sequences of any size and includes any number of mutations over the full length of SEQ ID NO 4.

17. Applicant's specification fails to provide guidance to the skilled artisan on the parameters for gene delivery for the breadth of the claimed invention. Numerous factors complicate the gene therapy art which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the

fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated.

Additionally, the specification does not provide any working examples which enable the claimed invention especially the derivative, fragment or mutant or variants of SEQ ID NO 4. Nor does the specification provide any guidance to the skilled artisan on how to make and use genetic constructs which would result in the desired effect. Even assuming that an effective genetic material is constructed, it is not evident that enough cells can be transfected to provide any therapeutic benefit.

Several recent reviews indicate that efficient delivery and expression of foreign DNA has not yet been achieved by any method. Verma et al (Nature, September 1997) teach that while the concept of gene therapy is simple, the actual practice of gene therapy has considerable obstacles (see abstract summary, page 239). Thomas et al (2003, Nature) that gene therapy has a history of controversy, especially in light of the fact that documented cases of leukemia like syndrome have been induced in patients who have received gene therapy (see abstract summary). Additionally, **Marshall** (*Science*, 269:1050-1055, August, 1995) states that "there has been no unambiguous evidence that genetic treatment has produced therapeutic benefits" (page 1050, column 1) and that "difficulties in getting genes transferred efficiently to target cells- and getting them expressed- remain a nagging problem for the entire field" (page 1054, column 3). James

Wilson , one skilled in the art, is quoted in the Marshall article as saying that "'[t]he actual vectors- how we're going to practice our trade- haven't been discovered yet" (page 1055, column 2). **Culver et al** (*TIG*, 10(5):174-178, May 1994, abstract), reviewing gene therapy for cancer, conclude that the "primary factor hampering the widespread application of gene therapy to human disease is the lack of an efficient method for delivering genes *in situ*, and developing strategies to deliver genes to a sufficient number of tumor cells to induce complete tumor regression or restore genetic health remains a challenge" (page 178). **Hodgson** (*Exp. Opin. Ther. Patents*, 5(5):459-468, May, 1995, abstract) discusses the drawbacks of viral transduction and chemical transfection methods, and states that "[d]eveloping the techniques used in animal models, for therapeutic use in somatic cells, has not been straightforward" (pages 459-460). **Miller et** al (*FASEB J.*, 9:190-199, 1995) also review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1).

What is now claimed is a method of making a vaccine preparation and a vaccine preparation composition comprising a nucleic acid, the nucleic acid not being required to be associated with a plasmid or viral vector. The specification fails to provide an enabling disclosure for the preparation and use of any nucleic acid vaccine because it fails to provide adequate guidance regarding how one would have prepared a nucleic acid which when introduced into a host would induce an immune response against the protein encoded by said nucleic acid. In contrast to direct protein immunogens, nucleic acids are required to target

appropriate cell types within a host, become transcriptionally active, appropriately process any encoded proteins and present such proteins to the host in a manner suitable for recognition by the host's immune system. Such a **"gene therapy"** approach to epitope delivery suffers from all the limitations associated with gene therapy technology. However, as of 12/95, the artisan did not accept, in the absence of suitable and particular guidance, that such could have been accomplished without having had to have exercised undue experimentation. See e.g. NIH Report Reference.

Therefore, even if the specification were enabled the construction of the gene delivery vehicle comprising a cell targeting element, in the absence of particular guidance, the artisan would have been required to develop *in vivo* and *ex vivo* means of practicing the claimed methods and such development in the nascent and unpredictable gene therapy art would have been considered to have necessitated undue experimentation on the part of the practitioner.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 78 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by EMBL Accession number AY004256, created date December 03, 2000.

EMBL accession number AY004256 discloses the instantly claimed nucleic acid obtained from Clostridium difficile encodes a Clostridium difficile slpA polypeptide, the AY004256 nucleic acid encoding a derivative, mutant, variant of SEQ ID NO 4, wherein SEQ ID NO 4 encodes a Clostridium difficile slpA polypeptide.

AY004256 anticipates the instantly claimed invention as now claimed, as the claimed vaccine only comprises a nucleotide sequence derivative, mutant or variant of SEQ ID NO 4.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

14. Claims 78, 89 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemaire et al, Genbank Accession number U79117, created date 1998.

(Instant claims 78 and 89) Lemaire et al, Genbank Accession number U79117 (see page 211, col. 1, last line) discloses the instantly claimed nucleic acid obtained from a Clostridium difficile variant strain (see title), specifically Clostridium thermocellum. The disclosed nucleic encodes a

Clostridium s-layer protein (slpA, see title, abstract) that therefore discloses a derivative, mutant, variant and fragment (see page 212, column 1, last paragraph and col. 2, paragraphs 1-2) of SEQ ID NO 4, wherein SEQ ID NO 4 encodes a Clostridium difficile slpA protein. Genbank Accession number U79117 anticipates the instantly claimed invention as now claimed, as the claimed vaccine only comprises a nucleotide sequence derivative, mutant, variant fragment of SEQ ID NO 4.

(Instant claim 122) Lemaire et al discloses a method of preparing a composition that comprises the steps of:

obtaining a C.difficile gene derivative, fragment, mutant variant, wherein the gene fragment was obtained from Clostridium thermocellum and encoded a SlpA protein. The gene fragment was amplified and cloned into a plasmid vector, which was subsequently transferred into E.coli (see page 212, col. 2, paragraph 2) thus

forming a preparation that comprised the gene derivative fragment, mutant variant which would be suitable for administration to a host.

The vector preparation and the attenuated (laboratory strain) E.coli strain preparation that comprises the gene fragment were formed to comprise the coding sequence fragment, derivative, mutant variant of SEQ ID NO 4 (see page 212, col. 2, paragraph 2). While the reference does not describe the preparation as a vaccine, the preparation was made by the claimed method, and the resultant preparation comprises all of the structural components recited in the instantly claimed invention. Therefore the method and preparation produced by the method of Lemaire et al inherently anticipate the instantly claimed invention as now claimed.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious

difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

15. Claims 78 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Sara et al (Feb. 2000).

Sara et al disclose the instantly claimed invention directed to compositions that comprise a nucleotide sequence derivative, mutant and variant of SEQ ID NO 4, SEQID NO 4 encoding a SlpA protein, wherein the compositions of Sara et al comprise nucleotide sequences that encode an Slp-A protein.

The gene designators include slpA and slpB (see Table 1, all species of gene shown encode derivative, mutant , variant genes of SEQ ID NO 4, the genes having been disclosed in Genbank, see all accession numbers) and therefore anticipate the instantly claimed invention directed to compositions that comprise derivative, mutant and variant nucleotide sequences of SEQ ID NO 4.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the

discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Bahl et al (1997) is cited to show Molecular Biology of S-layers..

18. US006350591B1, US 20020048816A1,US005874267A and WO99/51631 are cited to show SlpA (surface layer proteins) known in the art.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 14, 2005

L. R. F. Smith

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